Guidance for Industry

Guidance for Surgical Suture 510(k)s

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This document supersedes documents "Copy of October 9, 1992 Letter and Original Suture Labeling Guidance" dated/reformatted 12/17/97 and "Alternate Suture Labeling Resulting from the January 11, 1993 Meeting with HIMA" dated/reformatted 12/17/97.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Stephen P. Rhodes, HFZ-410, 9200 Corporate Boulevard, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Anthony D. Watson at (301) 594-3090 or by electronic mail at ADW@cdrh.fda.gov.

Additional Copies

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Guidance[1] for Surgical Suture 510(k)s

Purpose

The purpose of this guidance document is to assist those persons interested in submitting a premarket notification to FDA for surgical sutures. It serves as a supplement to "Premarket Notification 510(K): Regulatory Requirements for Medical Devices," (HHS Publication FDA 95-4158) and provides specific guidance regarding the information to be contained in a premarket notification submission for sutures described in 21 Code of Federal Regulations (CFR).

This guidance document replaces "Copy of October 9, 1992 Letter and Original Suture Labeling Guidance" dated/reformatted 12/17/97 and "Alternate Suture Labeling Resulting from the January 11, 1993 Meeting with HIMA" dated/reformatted 12/17/97.

Background

Prior to 1976, the Food and Drug Administration (FDA) regulated surgical sutures in the Center for Drugs. When the Medical Device Amendments (the Amendments) to the Federal Food, Drug, and Cosmetic Act (the Act) were passed in 1976, these products were classified as "transitional devices", statutorily placed in regulatory Class III, and reviewed under the premarket approval application (PMA) regulations.

In 1991, the Agency was petitioned for reclassification of the majority of sutures that were on the market at the time from Class III to Class II. As a result of this petition, several sutures were reclassified from Class III to Class II, and thus are no longer transitional devices.

The following is a list of procodes for sutures that are presently Class II and the dates that they were reclassified:

GAM	Absorbable Poly(glycolide/L-lactide) Surgical Suture	September 14, 1989
GAL	Absorbable Gut Suture	September 19, 1988
GAT	Nonabsorbable Poly(Ethylene Terephthalate)	July 5, 1990
GAW	Nonabsorbable Polypropylene Surgical Suture	July 5, 1990
GAR	Nonabsorbable Polyamide Surgical Suture	February 15, 1990
GAP	Natural Nonabsorbable Silk Surgical Suture	September 11, 1990
GAQ	Stainless Steel Surgical Suture	July 30, 1986
NBY	Nonabsorbable Expanded Polytetrafluoroethylene (ePTFE) Surgical Suture	April 18, 2000

[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Content

A 510(k) for a surgical suture should contain:

I. Introductory Information

A. The trade or proprietary name of the suture.

B. The common or usual name or classification name of the suture.

C. The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

D. The class in which the particular suture has been placed under section 513 of the Act and the panel (class II).

E. The name, address, and telephone number of the contact person responsible for the submission.

II. Indications for use form

III. Table of Contents

IV. Summary of information regarding safety and effectiveness upon which an equivalence determination can be made, or a statement that such information will be made available to interested persons upon request (21 CFR 807.93).

V. Truthful and accuracy statement (21 CFR 807.87(j)).

VI. Device description, with percentages of all materials (including coatings and additives) and United States Pharmacopeia 21 sizes of sutures to be marketed.

Note: Reference to U.S.P. is only possible when all U.S.P. specifications are met. if one or more specifications are not met, reference to U.S.P. cannot be used in the trade or generic name and the labeling should clearly state that suture is non- U.S.P. and in what respects it is non-U.S.P.

FDA considers surgical sutures to fall into two broad categories; absorbable and nonabsorbable. An absorbable suture when placed in the body is resorbed over a period of time. A nonabsorbable suture is one that is not resorbed by the body or does so over such a significant period of time as to be completely incorporated into the surrounding body tissue.

VII. Pre-Clinical Data

You should conduct all pre-clinical and clinical testing on the final, sterilized product. All suture submissions should contain data demonstrating that the sutures conform to the requirements set forth in the following United States Pharmacopoeia 21 (USP 21) tests:

- Monograph for Nonabsorbable Sutures or Monograph for Absorbable Sutures (as applicable);
- Sutures - Diameter <861>;
- Sutures – Needle Attachment <871>; and
- Tensile Strength <881>.

Alternatively, the submission may include a statement that the sutures conform to these tests (reference Agency's guidance entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" http://www.fda.gov/cdrh/ode/parad510.html).

A submission for an absorbable suture should contain either in-vivo or in-vitro test data that demonstrates the resorption profile of the final sterilized suture. The resorption profile should contain a chart, table, or graph that illustrates the tensile strength of the suture out to a "clinically significant" period of time. The term "clinically significant" depends on the suture's intended use. For instance, you should show that the resorption profile is consistent with the intended use, i.e., the medical repair, short-term approximation of tissue or long-term approximation of tissue. The numbers of sutures tested should be sufficient to provide a reasonable assurance that the tensile strength retention of the sutures will be consistent. This usually consists of data from at least the largest and smallest sizes of sutures, skipping no more than two size differences between tested sutures. For example, if you intend to market all suture sizes between 7 and 7-0, you should test at least the following sizes of suture for tensile strength retention: 7, 4, 1, 2-0, 5-0, and 7-0.

VIII. Clinical Data

New indications should be supported by clinical data. FDA will consider alternative data when supported by adequate scientific rationale.

IX. Sterilization

Regarding final sterilization procedures, the application should describe:

- the method of sterilization;
- the validation method for the sterilization cycle;
- the sterility assurance level (SAL) to be achieved; and
- the method for monitoring the sterility of each production lot.

If radiation sterilization is used, the sterilizing dose and methods for monitoring exposure level should be specified. If ethylene oxide (EtO) sterilization is performed, the application should describe methods by which residual levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol are determined and the amount of EtO and residues remaining on/in the device. Because EtO and its decomposition products may be very neurotoxic, specifications for EtO residuals should be set at a non-cytotoxic level. We recommend conforming to "Guidance for ANSI/AAMI/ISO 10993-7: 1995, Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals."

X. Labeling

Sample package inserts are provided for the suture types in the Appendices listed below. For other types of materials, this same general format should be followed.

Appendix A	Silk Suture
Appendix B	Stainless Steel Suture
Appendix C	Polyamide Suture
Appendix D	Poly(Ethylene Terephthalate) Suture
Appendix E	Poly(Glycolide/Lactide) Suture
Appendix F	Polypropylene Suture
Appendix G	Surgical Gut Suture
Appendix H	ePTFE Nonabsorbable Monofilament Suture

Appendix A - Silk Suture

PACKAGE INSERT (U.S.P. or NON-U.S.P.)

Description

_____ is a nonabsorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.]

[OPTION - THIS STATEMENT IS OPTIONAL AS USE OF OR REFERENCE TO U.S.P. IS ONLY POSSIBLE WHEN ALL U.S.P. SPECIFICATIONS ARE MET. IF ONE OR MORE SPECIFICATIONS ARE NOT MET, REFERENCE TO U.S.P. CANNOT BE USED IN THE TRADE OR GENERIC NAME AND THE LABELING SHOULD CLEARLY STATE THAT SUTURE IS NON-U.S.P. AND IN WHAT RESPECTS IT IS NON-U.S.P.]

_____ meets all requirements established by the United States Pharmacopeia f or Nonabsorbable Surgical Suture.

[END OF OPTION]

Indications

_____ is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Actions

_____ elicits an acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While _____ is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of all of the suture's tensile strength within one year.

Contraindications

The use of this suture is contraindicated in patients with known sensitivities or allergies to silk.

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, _____ should not be used where permanent retention of tensile strength is required, as in fixation of vascular prostheses.

Warnings

Do not resterilize. Discard open, unused sutures.

Prolonged contact of this or any other suture with salt solutions, such as those found in urinary or biliary tracts, may result in calculus formation.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing _____ for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

Adverse Reactions

Adverse effects associated with the use of this device include: wound dehiscence, gradual loss of all tensile strength over time, allergic response in patients that are known to be sensitive to silk, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, acute inflammatory tissue reaction, and pain, edema, and erythema at the wound site.

How Supplied

_____ is available in sizes _____ through _____. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.] The suture is supplied sterile in pre-cut lengths or ligating reels; both non-needled and affixed to various needle types; in one-, two-, and three-dozen boxes (or other suitable wording).

Appendix B - Stainless Steel Suture

PACKAGE INSERT (U.S.P. or NON-U.S.P.)

Description

_____ is a nonabsorbable sterile surgical suture composed of 316L stainless steel.

[OPTION - THIS STATEMENT IS OPTIONAL AS USE OF OR REFERENCE TO U.S.P. IS ONLY POSSIBLE WHEN ALL U.S.P. SPECIFICATIONS ARE MET. IF ONE OR MORE SPECIFICATIONS ARE NOT MET, REFERENCE TO U.S.P. CANNOT BE USED IN THE TRADE OR GENERIC NAME AND THE LABELING SHOULD CLEARLY STATE THAT SUTURE IS NON-U.S.P. AND IN WHAT RESPECTS IT IS NON-U.S.P.]

_____ meets all requirements established by the United States Pharmacopeia for Nonabsorbable Surgical Sutures.

[END OF OPTION]

Indications

_____ is indicated for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure.

Actions

_____ elicits a minima1 acute inflammatory reaction in tissues, and is not absorbed.

Contraindications

The use of this suture is contraindicated in patients with known sensitivities or allergies to the metals contained in 316L stainless steel, i.e., chromium, nickel, copper, cobalt, and iron.

Warnings

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing _____ for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted, surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Adverse Reactions

Adverse effects associated with the use of this device include: wound dehiscence, allergic response in patients with known sensitivities to metals contained in 316L stainless steel, i.e., chromium, nickel, copper, cobalt, and iron, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, and pain, edema, and erythema at the wound site.

How Supplied

_____ is available in sizes _____through _____. The suture is supplied sterile in pre-cut lengths or ligating reels; both non-needled and affixed to various needle types; in one-, two-, and three-dozen boxes (or other suitable wording).

Appendix C - Polyamide Suture

PACKAGE INSERT (U.S.P. or NON-U.S.P.)

Description

_____ is a nonabsorbable sterile surgical suture composed of the long-chain aliphatic polymers Nylon 6 and Nylon 6,6. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.]

[OPTION - THIS STATEMENT IS OPTIONAL AS USE OF OR REFERENCE TO U.S.P. IS ONLY POSSIBLE WHEN ALL U.S.P. SPECIFICATIONS ARE MET. IF ONE OR MORE SPECIFICATIONS ARE NOT MET, REFERENCE TO U.S.P. CANNOT BE USED IN THE TRADE OR GENERIC NAME AND THE LABELING SHOULD CLEARLY STATE THAT SUTURE IS NON-U.S.P. AND IN WHAT RESPECTS IT IS NON-U.S.P.]

_____ meets all requirements established by the United States Pharmacopeia for Nonabsorbable Surgical Suture.

[END OF OPTION]

Indications

_____ is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Actions

_____ elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While is not absorbed, progressive hydrolysis of the nylon in vivo may result in gradual loss of up to 20% of its tensile strength per year.

Contraindications

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, _____ should not be used where permanent retention of tensile strength is required, as in fixation of intraocular lenses or synthetic vascular grafts.

Warnings

Do not resterilize. Discard open, unused sutures.

Prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing _____for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

Adverse Reactions

Adverse effects associated with the use of this device include: wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, pain, edema and erythema at the wound site.

[ALTERNATIVE LANGUAGE OPTION

Adverse effects associated with the use of this device include: wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal acute inflammatory tissue reaction, and transitory local irritation.

END OF OPTION]

How Supplied

_____ is available in sizes ____ through ____. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.] The suture is supplied sterile in pre-cut lengths or ligating reels; both non-needled and affixed to various needle types; in one-, two-, and three-dozen boxes (or other suitable wording).

Appendix D - Poly(Ethylene Terephthalate) Suture

PACKAGE INSERT (U.S.P. or NON-U.S.P.)

Description

_____ is a nonabsorbable, sterile, surgical suture composed of Poly (Ethylene terephthalate). It is prepared from fibers of high-molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.]

[OPTION - THIS STATEMENT IS OPTIONAL AS USE OF OR REFERENCE TO U.S.P. IS ONLY POSSIBLE WHEN ALL U.S.P. SPECIFICATIONS ARE MET. IF ONE OR MORE SPECIFICATIONS ARE NOT MET, REFERENCE TO U.S.P. CANNOT BE USED IN THE TRADE OR GENERIC NAME AND THE LABELING SHOULD CLEARLY STATE THAT SUTURE IS NON-U.S.P. AND IN WHAT RESPECTS IT IS NON-U.S.P.]

_____ meets all requirements established by the United States Pharmacopeia (USP) for Nonabsorbable Surgical Sutures.

[END OF OPTION]

Indications

_____ is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Actions

_____ elicits a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. _____ is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

Contraindications

None known.

Warnings

Do not resterilize. Discard open, unused sutures.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing _____ for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

Adverse Reactions

Adverse effects associated with this device include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, and pain, edema, and erythema at the wound site.

[ALTERNATIVE LANGUAGE OPTION

Adverse effects associated with the use of this device include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal acute inflammatory tissue reaction, and transitory local irritation.

END OF OPTION]

How supplied

_____ is available in sizes ____ through ____. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.] The suture is supplied sterile in pre-cut lengths or ligating reels; both non-needled and affixed to various needle types; in one-, two-, and three-dozen boxes (or other suitable wording).

Appendix E - Poly(Glycolide/Lactide) Suture

PACKAGE INSERT (U.S.P. or NON-U.S.P.)

Description

_____ is a synthetic absorbable sterile surgical suture composed of homopolymers of glycolide or copolymers made from 90% glycolide and 10% L-lactide. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.]

[OPTION - THIS STATEMENT IS OPTIONAL AS USE OF OR REFERENCE TO U.S.P. IS ONLY POSSIBLE WHEN ALL U.S.P. SPECIFICATIONS ARE MET. IF ONE OR MORE SPECIFICATIONS ARE NOT MET, REFERENCE TO U.S.P. CANNOT BE USED IN THE TRADE OR GENERIC NAME AND THE LABELING SHOULD CLEARLY STATE THAT SUTURE IS NON-U.S.P. AND IN WHAT RESPECTS IT IS NON-U.S.P.]

_____ meets all requirements established by the United States Pharmacopeia (USP) for Synthetic Absorbable Surgical Suture.

[END OF OPTION]

Indications

_____ is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Actions

_____ elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of _____ synthetic absorbable sutures occurs by means of hydrolysis, where the polymer degrades to either glycolic acid or glycolic and lactic acids which are subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Implantation studies in animals indicate that _____ retains approximately ___% of its original tensile strength at two weeks post implantation, with approximately ___% remaining at three weeks. Absorption of _____ absorbable synthetic suture is essentially complete between ____ and _____ days. [Fill in the appropriate values].

Contraindications

This suture, being absorbable, should not be used where extended approximation of tissue is required.

Warnings

Do not resterilize. Discard open unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those-found in the urinary or biliary tracts, may result in calculus formation.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing _____ synthetic absorbable suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected wounds.

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching, or distention, or which may require additional support.

Precautions

Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

Adverse Reactions

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions -which may delay wound healing, wound infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation.

How Supplied

_____ synthetic absorbable suture is available in sizes ___ through ___. [Describe additional suture characteristics, i.e., suture configurations, packing fluid, dyes, coatings, etc., as appropriate.] The suture is supplied sterile in pre-cut lengths or on ligating reels, non-needled or attached to various needle types, in one-, two- or three-dozen boxes (or other suitable wording).

Appendix F - Polypropylene Suture

PACKAGE INSERT (U.S.P. or NON-U.S.P.)

Description

_____ is a nonabsorbable, sterile surgical suture composed of a strand of polypropylene, a synthetic linear polyolefin. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.]

[OPTION - THIS STATEMENT IS OPTIONAL AS USE OF OR REFERENCE TO U.S.P. IS ONLY POSSIBLE WHEN ALL U.S.P. SPECIFICATIONS ARE MET. IF ONE OR MORE SPECIFICATIONS ARE NOT MET, REFERENCE TO U.S.P. CANNOT BE USED IN THE TRADE OR GENERIC NAME AND THE LABELING SHOULD CLEARLY STATE THAT SUTURE IS NON-U.S.P. AND IN WHAT RESPECTS IT IS NON-U.S.P.]

_____ meets all requirements established by the United States Pharmacopeia for Nonabsorbable Surgical Sutures.

[END OF OPTION]

Indications

_____ is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Actions

_____ elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. _____ is not absorbed, nor is any significant change in strength retention known to occur in vivo.

Contraindications

None known.

Warnings

Do not resterilize. Discard open, unused sutures.

Prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing _____ for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

Adverse Reactions

Adverse effects. associated with the use of this device include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, and pain, edema, and erythema at the wound site.

How Supplied

_____ is available in sizes ____ through _____. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.] The suture is supplied sterile in pre-cut lengths or ligating reels; both non-needled and affixed to various needle types; in one-, two-, and three-dozen boxes (or other suitable wording).

Appendix G - Surgical Gut Suture

PACKAGE INSERT (U.S.P. or NON-U.S.P.)

Description

_____ is an absorbable sterile surgical suture composed of purified connective tissue (mostly collagen) derived from either the serosal layer of -beef (bovine) or the submucosal fibrous layer of sheep (ovine) intestines. (Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc. as appropriate.]

[OPTION - THIS STATEMENT IS OPTIONAL AS USE OF OR REFERENCE TO U.S.P. IS ONLY POSSIBLE WHEN ALL U.S.P. SPECIFICATIONS ARE MET. IF ONE OR MORE SPECIFICATIONS ARE NOT MET, REFERENCE TO U.S.P. CANNOT BE USED IN THE TRADE OR GENERIC NAME AND THE LABELING SHOULD CLEARLY STATE THAT SUTURE IS NON-U.S.P. AND IN WHAT RESPECTS IT IS NON-U.S.P.]

_____ meets all requirements established by the United States Pharmacopeia (USP) for Absorbable Surgical Sutures.

[END OF OPTION]

Indications

_____ is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Actions

When _____ surgical gut suture is placed in tissue, a moderate tissue inflammation occurs characteristic of foreign body response to a substance. This is followed by a loss of tensile strength and suture mass, as the proteolytic enzymatic digestive process dissolves the surgical gut. This process continues until the suture is completely absorbed. Many variable factors may affect the rate of absorption. Some of the major factors which can affect tensile strength loss and absorption rates are:

1. Type of suture-Plain gut generally is expected to absorb more rapidly than chromic gut.

2. Infection-Surgical gut is absorbed more rapidly in infected tissue than in non-infected tissue.

3. Tissue Sites-Surgical gut will absorb more rapidly in tissue where increased levels of proteolytic enzymes are present, as in the secretions exhibited in the stomach, cervix and vagina.

Contraindications

The use of this suture is contraindicated in patients with known sensitivities or allergies to collagen or chromium, as gut is a collagen based material, and chromic gut is treated with chromic salt solutions.

Warnings

Do not resterilize. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

This suture, being absorbable, should not be used where extended approximation of tissue is required.

Users should be familiar with surgical procedures and techniques involving gut suture before using _____ for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected wounds.

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

The use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching, or distention or which may require additional support.

Certain patients may be hypersensitive to collagen or chromium and might exhibit an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation.

Precautions

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

The surgeon should avoid unnecessary tension when running down knots, to reduce the occurrence of surface fraying and weakening of the strand.

Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Adverse Reactions

Adverse effects associated with the use of this device include: wound dehiscence, variable rates of absorption over time (depending on the type of suture used, the presence of infection and the tissue site), failure to provide adequate wound support in closure of sites where expansion, stretching or distension occur, etc., unless additional support is supplied through the use of nonabsorbable suture material, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from cancer, anemia, obesity, diabetes, infection or other conditions which may delay wound healing, allergic response in patients with known sensitivities to collagen or chromium which may result in an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation, infected wounds, moderate tissue inflammatory response characteristic of foreign body response, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation.

How Supplied

_____ is available in sizes ____ through _____. [Describe additional suture characteristics, i.e., packing fluid, dyes, coatings, etc., as appropriate.] The suture is supplied sterile in pre-cut lengths or ligating reels, both non-needled or affixed to various needle types; one, two- and three-dozen boxes (or other suitable wording).

Appendix H - ePTFE Nonabsorbable Monofilament Suture

Package Insert (Non-U.S.P.)

Description

A nonabsorbable, monofilament suture manufactured from polytetrafluoroethylene that has been expanded (ePTFE), to produce a porous microstructure which is approximately 50% air by volume. The porous nature of the ePTFE enables it to be swaged to needles that closely approximate the diameter of the thread, without compromising the strength of the needle attachment. The suture is undyed and contains no additives.

The ePTFE Suture differs from USP requirements. See the table below for diameter-strength relationship.

Actual ePTFE Suture Size	Mean ePTFE Suture Diam. (mm)	ePTFE Suture Knot-Pull Tensile Strength (kg)
0		
2-0		
3-0		
4-0		
5-0		
6-0		
7-0		
8-0		

USP Size	USP Diam. (mm) Min.	Max.	USP Limits on Avg. Knot-Pull Tensile Strength (kg)
0	0.35	0.399	2.16
2-0	0.30	0.339	1.44
3-0	0.20	0.249	0.96
4-0	0.15	0.199	0.60
5-0	0.10	0.149	0.40
6-0	0.070	0.099	0.20
7-0	0.050	0.069	0.11
8-0	0.040	0.049	0.06

Actions

PTFE has been shown in clinical trials to elicit minimal tissue reaction. The ePTFE Suture is not absorbed or subject to weakening by the action of tissue enzymes.

The internodal spaces of ePTFE permit infiltration of fibroblasts and leukocytes. Tissue attaches to and collagen penetrates into the ePTFE Suture.

Indications

The ePTFE Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery and dura mater repair. It is recommended for use where reduced suture line bleeding during cardiovascular anastomotic procedures is desired.

Contraindications

This device is contraindicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.

Warnings

Tissue invasion of the ePTFE suture can result in attachment of the suture to the tissue it penetrates. Such attachment may make removal of the suture difficult.

Precautions

Misuse of this suture, like any other suture, can result in severe injury or death to the patient. As with any suture, care should be taken to avoid damage when handling. Avoid crushing or crimping the suture with surgical instruments or exposing the suture to sharp edges.

Knot security requires standard surgical techniques of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. When tying knots with the ePTFE Suture, tension should be applied by pulling each strand of the suture in opposite directions with equal force. As the knot is tensioned, the air in the suture is forced out. Care should be taken to avoid using a jerking motion which could break the suture. Uneven tensioning of a well-formed square knot may result in an unsecure knot. When the ePTFE Suture is properly tensioned and formed, standard surgical knotting techniques will produce a secure knot.

Sterility

The ePTFE Suture is supplied STERILE unless the integrity of the package has been compromised. This device is for single use only. Do not resterilize.

Adverse Reactions

Potential adverse effects associated with the use of any suture include: wound dehiscence, infection, and localized transitory inflammatory tissue reaction.

Dosage and Administration

Use as required per surgical procedure.

How Supplied

Sutures are available as sterile strands in a variety of sizes and lengths, with and without permanently attached needles.

For single use only.